ACC.11
60th Annual Scientific Session & Expo

E499
JACC April 5, 2011
Volume 57, Issue 14

COMBINATION EZETIMIBE/SIMVASTATIN + EXTENDED-RELEASE NIACIN THERAPY IMPROVES ATTAINMENT OF RECOMMENDED LEVELS OF LDL-C, NON-HDL-C AND APO B IN HYPERLIPIDEMIC PATIENTS

ACC Poster Contributions
Ernest N. Morial Convention Center, Hall F
Sunday, April 03, 2011, 10:00 a.m.-11:15 a.m.

Session Title: Lipid Markers and Cardiovascular Risk
Abstract Category: 15. Pharmacology/Hormones/Lipids–Clinical
Session-Poster Board Number: 1011-298

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Background Concomitant targeting of LDL-C, non-HDL-C and apoB levels is suggested for subjects at high cardiovascular risk‡§.

Methods This analysis of a randomized, double blind study assessed the effect of ezetimibe/simvastatin (E/S) + extended release niacin (N) vs E/S and/or N on the attainment of specified LDL-C, non-HDL-C and apoB levels in type IIA/IIB hyperlipidemic (HL) subjects, and in subgroups with high CHD risk (+/-AVD), diabetes (DM), metabolic syndrome (MetS/nonDM) and nonDM/nonMetS. Patients received E/S 10/20mg + N to 2g or E/S 10/20mg for 64 wks, or N to 2g for 24 wks then E/S 10/20mg + N 2g or E/S 10/20mg for 40 wks more.

Results A significantly greater number of HL patients on E/S+N attained concomitant levels of LDL-C, non-HDL-C and apoB (cluster 1: <100, <130 and <90mg/dl for high CHD risk; cluster 2: <70, <100 and <80 mg/dl for very high CHD risk; table) compared with N and E/S at 24 wks and E/S at 64 wks. Attainment rates at 24 and 64 wks in all subgroups were significantly greater with E/S+N vs N, and generally numerically to statistically greater with E/S+N vs E/S. Greater attainment of all three specified lipid levels was most consistent with single level attainment of non-HDL-C (table).

Conclusion Our results indicate that combination E/S+N is an effective therapeutic option for improving attainment of lipid goals in HL patients. Attainment of non-HDL-C levels best supported concomitant attainment of all three lipid endpoints. The outcome benefits of E/S+N await results of ongoing clinical trials.

	% of patients attaining treatment levels				
	24 weeks			64 weeks	
	E/S+N†	E/S†	N†	E/S+N†	E/S†
Cluster 1: LDL-C <100mg/dl and nonHDL-C <130mg/dl and ApoB <90mg/dl‡					
Full cohort	77.3	54.6*	6.7*	77.3	57.1*
High risk w/o AVD	76.8	47.1*	2.0*	78.3	69.0
High risk w/ AVD	64.4	71.9	5.6*	66.7	59.3
DM	74.1	60.0	2.1*	79.6	75.0
MetS/nonDM	72.6	47.3*	7.1*	73.0	50.0*
NonDM/nonMetS	82.5	61.4*	8.4*	80.4	59.2*
Cluster 2: LDL-C <70mg/dl and nonHDL-C <100mg/dl and ApoB <80mg/dl§					
Full cohort	62.1	31.2*	1.8*	58.3	28.6*
High risk w/o AVD	62.5	38.2*	2.0*	60.9	41.4
High risk w/ AVD	46.7	40.6	2.7*	54.5	37.0
DM	63.8	40.0*	2.1*	61.2	41.7
MetS/nonDM	53.4	27.5*	3.6*	54.9	30.5*
NonDM/nonMetS	68.9	32.5*	1.2*	60.1	22.4*

† Number of patients assessed for E/S+S, E/S and N at 24 wks and E/S+N and E/S at 64 wks respectively in: Full cohort (383, 205,163, 321, 182); High risk w/o AVD (56, 34, 25, 46, 29); High risk w/ AVD (45, 32, 18, 33, 27); DM (58, 30, 23, 49, 24); MetS/nonDM (146, 91, 56, 122, 82); NonDM/nonMetS (177, 83, 83, 148, 76); ‡suggested for high-risk patients and §highest-risk patients with cardiometabolic risk (Brunzell JD et al, JACC 2008, 51:1512-24); * 95% CI for OR ratio for treatment comparison (E/S+N vs E/S or E/S+N vs N) excludes 1. Some variability in the results may be due to the small sample sizes in the subgroups. % attaining single treatment levels for LDL-C <70mg/dl, non-HDL-C <100 mg/dl and ApoB <80mg/dl in the full cohort at 24 wks were E/S+N (72.9, 78.8, 64.0%): E/S (49.5, 55.7, 32.2%); N (1.8, 5.4, 2.5%) and at 64 wks were E/S+N (65.3, 75.3, 64.8%); E/S (38.2, 51.7, 35.7%). % attainment for LDL-C <100mg/dl, non-HDL-C <130 mg/dl and ApoB <90mg/dl in the full cohort at 24 wks were E/S+N (90.5, 90.0, 77.3%); E/S (92.5, 90.1, 54.6%); N (18.7, 28.9, 7.4%) and at 64 wks were E/S+N (86.2, 86.2, 77.6%); E/S (86.0, 85.0, 57.7%)